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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/727,565 | 12/05/2003 | Thomas Piccariello | 54719.000099 | 9127 |

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

| EXAMINER | |
|---|---|
| RUSSEL, JEFFREY E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1654 | |

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/727,565 | PICCARIELLO ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey E. Russel | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040309*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: The claim for priority at page 1, section [001], of the specification is objected to because it recites that the instant application is a division of parent application 09/642,820. However, this application contains new matter with respect to the disclosure of the parent application. In particular, claims 8, 10, and 11 embrace a step of attaching an active agent to the N-terminus or the C-terminus of an amino acid, forming an N-carboxyanhydride from the resulting amino acid, and then polymerizing the N-carboxyanhydride. However, the original disclosure of the parent application is limited to attaching the active agent to the side chain of the amino acid where the polypeptide is to be formed by polymerizing the N-carboxyanhydride. See, e.g., page 5, lines 17-25; page 11, lines 19-21; and originally-filed claim 34. Where the active agent is to be attached to the N- or C-terminus of a polypeptide, the polypeptide is already formed when the active agent is attached to one of the polypeptide's termini. Claim 12 recites a step of "granulating", which embraces both dry and wet granulating. However, the original disclosure of the parent application is limited to wet granulating. See page 13, lines 13-14. As set forth in MPEP 201.06(c)(III), second full paragraph, where a copy of the oath or declaration from a prior application was filed in a continuation or divisional application, and if new matter is present relative to the prior application, (A) a new oath or declaration along with the surcharge set forth in 37 CFR 1.16(e) is required; and (B) the application must be redesignated as a continuation-in-part.

The status of the parent application in any claim for priority should be updated.

Appropriate correction is required.

Note that any change in the benefit claim filed in response to this requirement will not be timely filed within the time period set forth in 37 CFR 1.78(a)(2) or (a)(5). If the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the reference to the prior application must be made during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it is a copy of the declaration filed in parent application. However, as set forth in section 1 above, this application contains new matter relative to parent application 09/642,820. Accordingly, a new oath or declaration along with the surcharge set forth in 37 CFR 1.16(e) is required. See also MPEP 201.06(c)(III), second full paragraph.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preparing in which the active agent is attached to the side chain of the amino acid, does not reasonably provide enablement for a method of preparing in which the active agent is attached to the N-terminus or to the C-terminus of the amino acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claims 8 and 10-15 embrace attaching the active agent to the N- or C-terminus of the amino acid, forming an N-carboxyanhydride from the resulting amino acid, and then polymerizing the N-carboxyanhydride. However, when the active agent is attached to either terminus of the amino acid, the amino acid will not be able to undergo the N-carboxyanhydride formation reaction (see, e.g., Figure 4, which shows that lactamization

between the N- and C-termini is a necessary step in forming the N-carboxyanhydride). Applicants have not disclosed how the active agent can be attached to the N- or C-terminus of an amino acid so that the amino acid will still be capable of forming an N-carboxyanhydride.

4. Claims 1-7 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites administering "an amino acid/active agent complex comprising a polypeptide covalently attached to the active agent". However, "amino acid" contradicts "polypeptide", as an amino acid is not the same as, and is not generic to, a polypeptide. Further, "complex" contradicts "covalently", because "complex" implies some type of non-covalent attachment. Accordingly, it is not clear what is being administered to the patient in the method of claim 1. Claim 1 recites that the polypeptide is covalently attached to the active agent through an alcohol, an amine, or a carboxylic acid functionality. However, it is not clear if the alcohol, amine, or carboxylic acid functionality are to be provided by the polypeptide or by the active agent. The antecedent basis for the phrase "said amino acid" in claims 3 and 4 is unclear. It is not clear if this phrase refers to the amino acid/active agent complex, or to the amino acids which form the polypeptide. Claim 12 recites that in step (d), the complex is granulated. However, the complex no longer exists after (b), in which the complex has been converted into the N-carboxyanhydride. Alternatively, if Applicants intend to recite that the complex of step (a) is granulated, then it is questioned how the subsequent polymerizing of step (c) could be carried out with a granulated reactant.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of U.S. Patent No. 6,716,452. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '452 patent anticipate instant claims 1-5 and 7. With respect to instant claim 6, while the '452 patent does not claim inclusion of a microencapsulating agent with the orally administered active agent-polypeptide, it would have been obvious to one of ordinary skill in the art to orally administer the claimed active agent-polypeptide of the '452 patent in combination with a microencapsulating agent because microencapsulating agents are well known in the pharmaceutical arts as being useful for the oral administration of active agents.

7. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 40-42, 46, 49, 51, and 57-121 of copending Application No. 10/156,527. Although the conflicting claims are not identical, they are not patentably distinct from each other. It would have been obvious to one of ordinary skill in the art to administer the claimed compositions, e.g., of claim 57, 75, and 114, of the '527 application in accordance with their claimed intended uses. With respect to instant claim 6, while the '527 application does not claim inclusion of a microencapsulating agent with the orally administered hydrocodone-carrier peptide, it would have been obvious to one of ordinary skill in

the art to orally administer the claimed hydrocodone-carrier peptide of the '527 application in combination with a microencapsulating agent because microencapsulating agents are well known in the pharmaceutical arts as being useful for the oral administration of active agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 75, 76, and 135-194 of copending Application No. 09/933,708. Although the conflicting claims are not identical, they are not patentably distinct from each other. It would have been obvious to one of ordinary skill in the art to administer the claimed compositions, e.g., of claims 135-194, of the '708 application in accordance with their claimed intended uses. With respect to instant claims 5 and 6, while the '708 application does not claim administration in the form of an ingestible tablet, a capsule, or an oral suspension, and does not claim inclusion of a microencapsulating agent with the orally administered zidovudine-polypeptide/amino acid, it would have been obvious to one of ordinary skill in the art to orally administer the claimed zidovudine-polypeptide/amino acid of the '708 application in the form of an ingestible tablet, a capsule, or an oral suspension, or in combination with a microencapsulating agent, because ingestible tablets, capsules, and oral suspensions are well-known forms for oral administration of pharmaceutical agents, and because microencapsulating agents are well known in the pharmaceutical arts as being useful for the oral administration of active agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Instant claims 1-7 and 9 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/642,820 because the parent application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

Instant claims 8 and 10-15 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/642,820 because the parent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a step of attaching an active agent to the N-terminus or the C-terminus of an amino acid, forming an N-carboxyanhydride from the resulting amino acid, and then polymerizing the N-carboxyanhydride; and does not disclose granulating in general.

Accordingly, the WO Patent Application 02/34237 is available as prior art against instant claims 8 and 10-15 under 35 U.S.C. 102(b).

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

11. Claims 8 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 02/34237. The WO Patent Application '237 teaches attaching an active agent to the side chain of an amino acid such as glutamic acid or a synthetic amino acid, forming an N-carboxyanhydride from the modified amino acid, and then polymerizing the N-carboxyanhydride. The resultant active agent-polypeptide can be granulated to form a tablet for oral administration. See, e.g., page 27, lines 6-13; page 29, lines 13-14; and claims 34-40.

12. Claims 8, 9, and 13-15 are rejected under 35 U.S.C. 103(a) as being obvious over Hirschmann et al (U.S. Patent No. 3,846,399) in view of Toth et al (U.S. Patent No. 5,882,645). Hirschmann et al teach forming polypeptides by sequential reaction of N-carboxy amino acid anhydrides. The amino acids can be tyrosine, arginine, threonine, and glutamic acid, and the sidechains of the amino acids can be derivatized. See, e.g., the Abstract and column 10, lines 13-39. Hirschmann et al do not teach forming polypeptide in which the sidechains are derivatized with active agents such as pharmaceutical agents. Toth et al teach forming polypeptides by sequential reaction of amino acids by any conventional peptide synthesis method, in which at

least two of the amino acid sidechains are derivatized with lipophilic moieties in order to impart antigenicity to the resulting polypeptide. See, e.g., the Abstract; column 3, lines 12-29; column 6, lines 8-15, 28-30, and 46-52; and column 7, lines 44-47. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to perform the synthesis of Hirschmann et al using the lipophilic moiety-derivatized amino acids of Toth et al because the synthesis of Hirschmann et al is applicable to any derivatized amino acids, because the polypeptides of Toth et al can be synthesized using any conventional peptide synthesis method, and because use of the derivatized amino acids of Toth et al in the synthesis method of Hirschmann et al will permit the production of antigenic polypeptides, which are useful in the vaccine arts.

13. Claims 1-4, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (U.S. Patent No. 5,534,496). Lee et al teach administering drugs in combination with N-protected peptides so that drug transport across epithelial cells at mucosal sites is enhanced. The drug can be conjugated to the peptide, can be microencapsulated or combined with carriers and other inactive components or tableted, and can be administered orally. The peptide can be comprised of naturally occurring amino acids (e.g., Glu) and of synthetic amino acids (i.e. D-Arg). The drug can be conjugated to the peptide via a chemical linkage such as a peptide bond that is cleaved in the bloodstream or other sites in the body after passage across the epithelial cells. See, e.g., the abstract; column 2, line 55 - column 3, line 35; column 4, lines 17-25; column 8, lines 29-39; column 8, line 65 - column 9, line 15; and the claims. Amino acids contained in the N-protected peptide, or the N-protected peptide itself, correspond to Applicants' adjuvants which activate an intestinal transporter. Because of the similarity in structure and

composition between the conjugate, the drug, and the N-protected peptides of Lee et al and the polypeptide and active agent claimed by Applicants, inherently the conjugates of Lee et al will be capable of release of the drug into the bloodstream following oral administration to the same extent claimed by Applicants.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being obvious over Lee et al (U.S. Patent No. 5,534,496) as applied against claims 1-4, 6, and 7 above, and further in view of Wallace et al (U.S. Patent No. 5,238,714). To the extent that Lee et al do not teach administering their conjugates in microencapsulated form, Wallace et al disclose microencapsulation of therapeutic agents such as cytotoxic agents in order to affect the release rate of the therapeutic agents. See, e.g., column 4, lines 12-47. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to microencapsulate the conjugates of Lee et al as taught by Wallace et al because Wallace et al teach that it would have been desirable to be able to control the release rate of therapeutic agents.

15. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/04277. The WO Patent Application '277 teaches a prodrug of the formula recited at page 6, lines 1-21, in which a therapeutic agent, in particular AraC, is attached via its amine group to the C-terminus of a peptide having from two to eleven amino acids. The amino acids in the peptide can be synthetic, and are chosen to control the rate of cleavage of the peptide from the therapeutic agent. In compound 19, the peptide is comprised of two different synthetic amino acids, Aib and Azagly. The prodrugs can be administered orally. The WO Patent Application '277 also teaches attachment of the peptide to the therapeutic agent through a reactive hydroxyl function of the therapeutic agent. See, e.g., page 3, line 24 - page 4, line 2;

page 7, lines 19-21; page 7, line 29 - page 8, line 7; page 12, lines 17-19; page 15, lines 8-11; and page 16, lines 7-10. In view of the similarity in structure and method of administration between the prodrugs of the WO Patent Application '277 and Applicants' claimed method, the prodrugs of the WO Patent Application '277 are deemed to anticipate Applicants' claimed compositions and are deemed inherently to release the active agent into the bloodstream by enzymatic action following oral administration. Sufficient evidence of similarity is deemed to be present between the prodrugs of the WO Patent Application '277 and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than that of the WO Patent Application '277.

16. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/04277 as applied against claim 1 above, and further in view of Wallace et al (U.S. Patent No. 5,238,714). The WO Patent Application '277 does not teach administration in the form of an ingestible tablet, a capsule, or an oral suspension, and does not teach inclusion of a microencapsulating agent with the orally administered prodrugs. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to orally administer the claimed prodrugs of the WO Patent Application '277 in the form of an ingestible tablet, a capsule, or an oral suspension, because ingestible tablets, capsules, and oral suspensions are well-known forms for oral administration of pharmaceutical agents. Wallace et al disclose microencapsulation of therapeutic agents such as cytotoxic agents in order to affect the release rate of the therapeutic agents. See, e.g., column 4, lines 12-47. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to microencapsulate

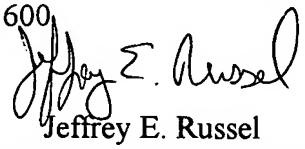
the prodrugs of the WO Patent Application '277 as taught by Wallace et al because Wallace et al teach that it would have been desirable to be able to control the release rate of therapeutic agents.

17. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by the Nishida et al article (Pharmaceutical Research, Vol. 11, pages 160-164). The Nishida et al article teaches oral administration of salicylic acid covalently attached to the dipeptide Gly-Gly. The salicylic acid is enzymatically released into the bloodstream after administration. See, e.g., the Abstract and Table III.

18. The references crossed off of pages 1 and 2 of the Information Disclosure Statement filed March 9, 2004 are duplicate citations. The reference crossed off of page 3 of the Information Disclosure Statement filed March 9, 2004 has not been considered because the citation is incomplete. Either the document number is incomplete, or else the publication date has been inserted in place of the document number and no document number has been provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
January 13, 2005